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| 10/690,384 | 10/20/2003 | Curtis Wright IV | 6750-237-99 | 2381 |

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| EXAMINER | |
|---|---|
| MERCIER, MELISSA S | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/690,384 | WRIGHT, CURTIS | |
| | Examiner | Art Unit | |
| | MELISSA S. MERCIER | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19 and 23-44* is/are pending in the application.

4a) Of the above claim(s) *24,27 and 29-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,23,25,26 and 28* is/are rejected.

7)☐ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Summary

Receipt of Applicants Remarks and Amended Claims filed on April 17, 2009 is acknowledged. Claims 1-19, 23-44 are pending in this application. Claims 24 and 27, and 29-44 remain withdrawn. Claims 1-19, 23, 25-26, and 28 remain under prosecution. Applicant's arguments regarding the status of claim 28 are persuasive. Therefore, claim 28 has been rejoined and now under prosecution in this office action.

### *Withdrawn Rejections*

#### *Claim Rejections – 35 USC § 103*

The rejection of claims 1-5, 7-19, 23 under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Cleary et al. (US Patent 5,006,342) has been withdrawn in view of Applicants amendment to the claims adding the limitation "an impermeable layer on the surface of the backing layer".

The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Cleary et al. (US Patent 5,006,342) and further in view of Katz et al. (US Patent 5,028,435) has been withdrawn in view of Applicants amendment to the claims adding the limitation "an impermeable layer on the surface of the backing layer".

### *Maintained Rejections*

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Cleary et al. (US Patent 5,006,342).

Pagedas teaches a transdermal segmented dosage unit for administering a dosage of a pharmaceutical to the skin of a patient. The dosage unit includes a backing layer which is non-permeable with respect to a pharmaceutical to be administered by the dosage unit and extends coextensively with the patch prior to removal (corresponding to Applicants release liner), a membranous layer that is permeable to the pharmaceutical, a biologically acceptable adhesive, an impermeable coating means for dividing and severing the dosage unit into pre-selected segmental areas corresponding to fractional dosages of pharmaceutical (which corresponds to Applicants backing layer).

The fractional dosages may be administered in any pre-selected combination (abstract).

Pagedas discloses the adhesive serves to adhere the dosage unit to the skin of the patient receiving the dosage and may be over the entire surface of the porous membrane or may define an adhesive free zone (column 3, lines 20-35). Therefore, it is the position of the examiner that the membrane comprising the pharmaceutical may or may not have adhesive on it, however, the borders, as shown in figures 1-2 and 4-6 would have an adhesive layer, which are the same as the instant drawings.

The pharmaceutical dosage layer may be micro dispersed on the surface of the permeable membrane (column 3, lines 48-50). Additionally, the permeable membranous material to be used in the permeable membrane layer is best described as a plurality of conjoining porous particles which provide a supporting structure while providing a dispersion of microscopic sized interconnecting pores (column 3, lines 37-41).

Regarding claim 2, it is the position of the examiner that a skilled artisan would have the knowledge to apply the patch to any area of interested on the patient's skin in order to achieve the desired treatment from the patch. Furthermore, Figure 6 shows 2 patches being applied to the torso an individual.

Regarding claims 12-19, Pagedas's transdermal dosage unit, discloses, "a series of perforations or alternately, scoring lines, with purpose to divide the dosage unit into a series of dose specific segments. Thus the dosage unit patch may be used in its entirety for the full dosage, or in the alternative, may be separated along perforate or scored lines to reduce the dosage received by a predetermined amount" (column 1, lines 50-55). It is the examiners position that the skilled artisan would also be able to manufacture the patches in whatever size, shape, and amount of units desired. It would also be within the knowledge of the skilled artisan to package the patches in any way deemed appropriate including reseal able packages. Applicant's attention is directed to Pagedas's drawings for a clear representation of the dosage units. Applicants attention is directed to MPEP 2144.04 IV, in which the court held that changes to dimensions where the dimensions would not perform differently are not patentably distinct over the prior art. Furthermore the recitation of packaging components in which the transdermal

patch are stored, do not provide a patentable distinction between the prior art patch and the instant patch since the packaging do not change the performance characteristics and thus a material effect on the method of using/treatment.

Pagedas does not teach the pharmaceutical agent to be buprenorphine in a drug in matrix or a drug in adhesive or the use of a softening agent selected from dodecanol, undecanol, octoanol, esters of carboxylic acids or combinations thereof.

Clearly discloses a laminated composite for administration of a drug trandermally (abstract). The patch comprises a lamina of a pharmaceutically acceptable pressure-sensitive adhesive optionally in which a drug or agent is dispersed or dissolved within. The pressure sensitive adhesive lamina provides no rate controlling barrier to diffusion of the drug or agent for the device to the skin (column 2, lines 48-59).

Regarding claim 4, the drug may comprise any therapeutic, prophylactic or other beneficial pharmaceutical and or physiological effect on the wearer, such as opioid and includes buprenorphine, fentanyl, fentanyl analogs, naloxone, and codeine (column 6, lines 1-6).

Regarding claim 11, the transdermal patch may comprise a permeation enhancing amount of a fatty acid ester or fatty alcohol of a C2 to C4 alkanediol (column 3, lines 7-13).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the transdermal segmented dosage units taught by Pagedas with the agent taught by Cleary in order to provide a method of delivering buprenorphine to a patient and "if the patient is unable to tolerate the full dosage, may

use any fractional dosage obtainable by separating out the appropriate fractional dose from the total dosage patch. The fractional doses unused after separation may be used at a later time, thus reducing waste" (Pagedas, column 1, lines 61-65).

Applicant would have a reasonable expectation of success since both references teach the use of transdermal patches for administering a drug to a patient.

Regarding the limitations of claims 7-9, the instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of the drug, to prepare a composition for topical administration because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues Pagedas does not teach or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer, wherein the borders are free of any drug, as recited in amended claims 1, 25 and 26, respectively. In addition, Pagedas does not disclose or suggest a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer as recited in amended claim 1, buprenorphine as recited in amended claim 25, or a narcotic analgesic as recited in amended claim 26.

The examiner disagrees with Applicants assessment of the Pagedas reference. Pagedas discloses the adhesive serves to adhere the dosage unit to the skin and may be over the entire surface or may define an adhesive free surface (column 3, lines 20-35). Applicant's attention is drawn to the drawings which show the membrane with a border around it consisting of the impermeable coating layer. Since the drug of the dosage unit is confined to the membrane, one of ordinary skill in the art would determine that the border would comprise the adhesive material without drug admixed therein.

Applicant has pointed to figures 3 and 3a as evidence of the drug being fully included in any adhesive strip. The examiner disagrees with Applicants assessment of the scope of the teachings regarding the drawing. Figures 1-2 and 4-6 clearly show a border surrounding the membrane comprising the drug. Therefore, it is the position of the examiner that one of ordinary skill would determine this border to comprise an adhesive strip without a drug admixed in since the drug is limited to the membranous layer of the patch.

While it is conceded that the Pagedas reference does not teach the pharmaceutical agent to be buprenorphine in a drug in matrix or drug in adhesive layer or the use of a softening agent selected from dodecanol, undecanol, octoanol, esters of carboxylic acids or combinations thereof, the teachings of these limitations are in the Cleary reference.

While it is acknowledged that the Cleary reference's transdermal patch has a substantially different structure from the Pagedas reference, it is not being relied for the structural limitations. Those limitations are disclosed in the Pagedas reference. Cleary is relied on the for the disclosure of the pharmaceutical agent buprenorphine in a drug in matrix or drug in adhesive layer and the use of a softening agent selected from dodecanol, undecanol, octoanol, esters of carboxylic acids or combinations thereof to be well known in transdermal applications.

***Newly Applied Rejections/Objections***

***Claim Objections***

Claim 10 is objected to because of the following informalities: It appears Applicant has misspelled octanol. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

Claims 1-19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (US Patent 4,573, 996) in view of Pagades et al. (US Patent 6,221,384).

Kwiatek discloses a device for the administration of an active agent to the skin or mucosa. The device includes an impermeable adhesive layer which surrounds the permeable adhesive layer of the device and which with the outer surface layer of the device forms a pocket so that, when the device is adhered to the skin or mucosa, the active agent can be released to the skin or mucosa to provide a continuous dose of the active agent to the skin or mucosa but cannot permeate through the outer surface layer or radially outwardly through the active agent impermeable adhesive layer (abstract).

In preferred embodiments, the reservoir is formed from a backing member and a membrane sealed to the backing member so as to create the reservoir between the membrane and the backing member. The active agent permeable adhesive layer is on the membrane and is adapted to adhere to the skin or mucosa, and the active agent is contained in the reservoir. Preferably, the outer surface layer in such embodiment is an overlay covering layer which is coated on one surface with the active agent impermeable adhesive layer to create an impermeable adhesive surface. This impermeable adhesive surface has a sufficient surface area and is of a shape so that the impermeable adhesive surface overlaps completely the backing member. This impermeable adhesive surface is adhered to the backing member so that the impermeable adhesive surface provides the active agent impermeable adhesive layer

which surrounds the perimeter of the active agent permeable adhesive layer and forms the pocket with the overlay covering layer (column 2, lines 51-68).

Regarding claim 2, the device is to be applied to the skin. Example 1 discloses its application to the chest area (column 13, lines 50-51).

Regarding claim 3, a protective layer is disposed on the permeable and impermeable adhesive layers (column 4, lines 59-60).

Regarding claim 4, morphine is disclosed as a suitable active agent (column 11, line 1).

Regarding claims 6 and 10-11, the active agent, whether in the presence or absence of a carrier, can be combined in the reservoir or a plurality of microcapsules with a transporting agent which assists the drug delivery to achieve administration of a drug to a receptor such as by enhancing penetration through the skin. Transporting agents include aliphatic alcohols having 4-12 carbon atoms (column 11, lines 44-48), which encompass Applicants claimed species.

Regarding claims 7-9, the percentage of the drug within the drug layer is not disclosed, however, it would have been obvious and within the skilled artisan's knowledge to optimize the amount of drug contained within the reservoir in order to obtain desired therapeutic benefits.

Kwiatek does not disclose a plurality of the patch units connected to each other along one or more borders of the patch units.

Pagedas teaches a transdermal segmented dosage unit for administering a dosage of a pharmaceutical to the skin of a patient with means for dividing and severing the dosage unit into pre-selected segmental areas corresponding to fractional dosages of pharmaceutical. The fractional dosages may be administered in any pre-selected combination (abstract).

Regarding claims 12-19, Pagedas's transdermal dosage unit, discloses, "a series of perforations or alternately, scoring lines, with purpose to divide the dosage unit into a series of dose specific segments. Thus the dosage unit patch may be used in its entirety for the full dosage, or in the alternative, may be separated along perforate or scored lines to reduce the dosage received by a predetermined amount" (column 1, lines 50-55). It is the examiners position that the skilled artisan would also be able to manufacture the patches in whatever size, shape, and amount of units desired. It would also be within the knowledge of the skilled artisan to package the patches in any way deemed appropriate including reseal able packages. Applicant's attention is directed to Pagedas's drawings for a clear representation of the dosage units. Applicants attention is also directed to MPEP 2144.04 IV, in which the court held that changes to dimensions where the dimensions would not perform differently are not patentably distinct over the prior art. Furthermore the recitation of packaging components in which the transdermal patch are stored, do not provide a patentable distinction between the prior art patch and the instant patch since the packaging do not change the performance characteristics and thus a material effect on the method of using/treatment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the geometry of Kwiatek device to prepare segmented dosage units as taught by Pagedas in order to provide the appropriate dosage of the drugs to be administered as taught by Pagedas thereby eliminating waste and cost to the patient.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615